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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,945	06/15/2001	Victor Lyamichev	FORS-04586	9139
23535	7590	04/09/2004	EXAMINER	
MEDLEN & CARROLL, LLP 101 HOWARD STREET SUITE 350 SAN FRANCISCO, CA 94105			MYERS, CARLA J	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 04/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/882,945

Applicant(s)

LYAMICHEV ET AL.

Examiner

Carla Myers

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-26 is/are allowed.
- 6) ☒ Claim(s) 15 and 27-43 is/are rejected.
- 7) ☒ Claim(s) 15, 27 and 43 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5/13/03.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

1. The allowability of claims 1-43 is withdrawn. As indicated in the letter of March 31, 2004, prosecution in this application is being re-opened. Upon further consideration, the following grounds of rejection are being applied. This action is made non-final.

Claim Objections

2. Claims 15, 27 and 43 are objected to because the claims do not properly depend from claims 1, 16 and 28, respectively, since a claim to a product can not depend from a method of using a product. As set forth in MPEP 608.01(n), the test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. The test is not whether the claims differ in scope. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim. In the present case, the dependent claims to compositions comprising a probe do not require every limitation of the parent method claims and the claims to the compositions can be infringed upon without infringing the subject matter of the methods.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 28-43 are indefinite over the recitation of "wherein said length of said amplification products provides a distance of an accessible site on said target nucleic

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acid from said first domain" because it is unclear as to what is intended to be encompassed by this phrase. In particular, it is unclear as to what is intended to be meant by "a distance of an accessible site" and it is unclear as to how this distance is to be used to determine the location of the accessible site. For example, it is unclear as to whether this phrase refers to the length of the accessible site, the distance from the end of the amplification product to the beginning or end of the accessible site or the distance between the end/beginning of the extension primer and the end/beginning of the first domain or the end/beginning of the region that the second amplification primer binds to in the first domain.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 27 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Britschgi et al (U.S. Patent No. 5,770,373; June 23, 1998).

The claims are drawn to compositions comprising an oligonucleotide wherein the oligonucleotide comprises a sequence of a first region of a primer selected by the claimed methods for identifying primers and compositions comprising oligonucleotides which comprise a region complementary to an accessible site identified by the claimed methods. Thereby, the claims include compositions comprising oligonucleotides which are complementary to accessible sites. The method steps recited in claims 1, 16 and 28

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are not "read-into" the composition claims and these method steps do not further define any specific structural features of the oligonucleotides.

Britschgi et al teach compositions comprising oligonucleotides which specifically hybridize to regions of RNA that do not contain secondary structure (see, for example, Tables 2-5; column 14, lines 1-14; and column 26, lines 29-32). As such, the primers of Britschgi are complementary to accessible regions of target RNA. For example, at column 29, Britschgi teaches an oligonucleotide MTB030, which is complementary to a region of *M. tuberculosis* RNA that consists of a single-stranded region (as opposed to the MTB034 oligonucleotide which binds to a region of double-stranded RNA). Britschgi also teaches amplification of RNA using the oligonucleotides to the accessible regions (see, for example, column 31). Accordingly, Britschgi teaches compositions comprising oligonucleotides complementary to accessible regions, and these accessible regions are the same as those which could be identified by the present methods of claims 1, 16 and 28.

5. Claims 15, 27 and 43 are rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al (U.S. Patent No. 5,846,723; December 8, 1998).

The claims are drawn to compositions comprising an oligonucleotide wherein the oligonucleotide comprises a sequence of a first region of a primer selected by the claimed methods for identifying primers and compositions comprising oligonucleotides which comprise a region complementary to an accessible site identified by the claimed methods. Thereby, the claims include compositions comprising oligonucleotides which are complementary to accessible sites. The method steps recited in claims 1, 16 and 28

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are not "read-into" the composition claims and these method steps do not further define any specific structural features of the oligonucleotides.

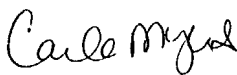
Kim et al teach compositions comprising oligonucleotides which specifically hybridize to regions of RNA that are accessible and do not contain secondary structure (see, for example, Table II; column 15, lines 13-41; and column 21, the first paragraph of "Example 2"). As such, the primers of Kim are complementary to accessible regions of target RNA. Kim teaches methods for identifying accessible regions of RNA using an RNase H cleavage reaction and teaches making oligonucleotides that are complementary to the identified accessible regions. Accordingly, Kim teaches compositions comprising oligonucleotides complementary to accessible regions, and these accessible regions are considered to be the same as those which could be identified by the present methods of claims 1, 16 and 28.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (571) 272-0747. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)-272-0782.

Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Carla Myers
April 5, 2004


CARLA J. MYERS
PRIMARY EXAMINER